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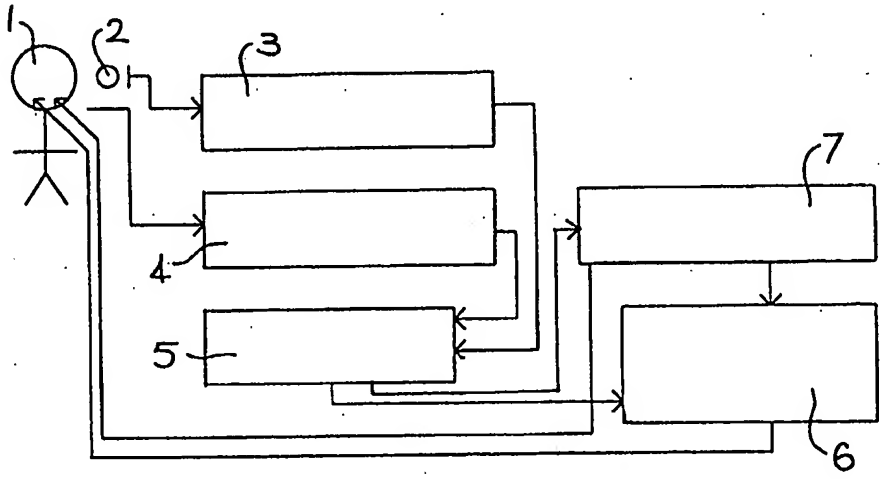

(57) Abstract

Apparatus for controlling gas or drug delivery to a patient, said delivery being adapted to maintain effective respiratory function. The apparatus includes means (2, 3, 4) for monitoring one or more physiological variables such as breathing airflow sound, EEG, EOG, EMG and/or patient position associated with the patient. The apparatus also includes means (4) for deriving from the variables, data representing a physiological state associated with the patient and means (5) for determining from the data, a gas pressure or drug quantity which substantially prevents a deterioration in the state. The determining means may include an algorithm adapted to generate a gas pressure signal which is substantially 180° out of phase relative to the phase of the patient breathing and/or sound. The apparatus may include a gas delivery means (6) for delivering gas to the patient in accordance with the determined gas pressure. The apparatus may include a drug delivery module (7) for delivering a drug to the patient.

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CONTROLLING GAS OR DRUG DELIVERY TO PATIENT

The present invention relates to apparatus for controlling gas delivery to a patient. The apparatus of the present invention is related to apparatus disclosed in applicant's copending PCT application AU96/00679 filed 31 October 1996 and in AU Patent 632932 entitled "Analysis System for physiological variables", the disclosures of which are incorporated herein by cross reference.

The apparatus of the present invention may provide a diagnostic and/or a therapeutic function. The diagnostic function may include monitoring and/or diagnosis of physiological variables associated with the patient. The therapeutic function may include application of controlled gas delivery to the patient. The diagnostic and therapeutic functions may be performed in a single device having integrated functions or it may be performed via two or more separate devices.

The apparatus of the present invention is particularly useful for investigation, diagnosis and treatment of sleep, respiratory and sleep related respiratory disorders, sleep propensity, fatigue and asthma and will be described herein in that context. Nevertheless it is to be appreciated that it is not thereby limited to such applications.

The apparatus of the present invention has been developed for, but is not limited to monitoring, analysing, storing, controlling and networking physiological variables. The aforementioned "controlling of physiological variables" includes controlling the gas delivery to a patient. This gas can be but is not limited to air as used in a CPAP (Continuous Positive Air Pressure) application, or one of the many variations of positive air pressure delivery to a patient known in the art.

Due to the complex and varying states of sleep and the broad range of sleep disorders that can be diagnosed, many different physiological variables and events can be simultaneously monitored, analysed and stored by the present

apparatus. The monitored physiological variables and events can include one or more channels of each of the following signal types:

• Breathing and snoring sounds	
• CPAP mask sound	(monitoring for patients breathing sounds within CPAP mask). These sounds include snoring, wheezing and other disordered breathing sounds
• Brain waves/Electroencephalogram	(EEG)
• Eye Movement/Electro-oculogram	(EOG)
• Muscle function/Electro-myogram	(submental EMG from muscles under the chin)
• Muscle function/Electro-myogram	(diaphragm EMG from respiratory effort)
• Muscle function/Electro-myogram	(other EMG reflecting muscle and nerve activity either by invasive or non-invasive monitoring)
• Status of patient position	
• Leg movements	(Left and/or Right legs)
• Heart beat/Electrocardiogram	(ECG)
• Oximetry	($S_a O_2$ - Oxygen saturation)
• Carbon dioxide monitoring	CO_2
• Respiratory effort	(Abdominal, thoracic or otherwise)
• Airflow	(Nasal or oral)
• Continuous Positive Airflow Pressure	(monitoring of patients mask pressure during application of CPAP treatment)
• CPAP mask temperature	(monitoring of CPAP mask air temperature for breathing activity and airflow of patient)

- Status of lights
- Graphic processing of video image (allows determination of whether patients eyes are open or closed).
- Patient digital video recording and graphic processing techniques for determination of eye lid activity (ie status of patient eyes being opened or closed - relative to fully closed or fully opened eyes status).
- Time and date stamping of monitored physiological data, video and sound.
- Infrared Video monitoring (for night studies)
- Complex sound analysis (accurate full bandwidth or limited bandwidth recording and analysis of breathing sounds. The sound is analysed and compared with criteria or a data base, consisting of reference data for disordered breathing. Microphones may be servo controlled for automatic axis adjustment to allow optimum focus on breathing sounds.)
- Physiological events: ie ECG arrhythmia, EEG spike detection, EEG spindles amongst others
- Local area networked monitoring, analysis and/or storage of a patient's physiological variables
- Endoscopy
- Breath by breath analysis-pnuemotachograph
- 3 D imaging
- Virtual patient monitoring
- Infrared eye detection for fatigue and sleep monitoring
- EEG delta and alpha-wave detection
- Eye position and movements by way of Infrared Eye Detection
- Delta Wave detections and related sleep/fatigue/impairment detection
- Mattress Device: monitoring of patient sleep state and respiratory parameters by using a mattress sensor device. The matress device can be used to monitor a patient's electro-oculogram, sleep state, arousals, position, electrocardiogram. There are presently two types commercially available mattress devices; Static Charge-sensitive Bed (SCSB) and polyvinylidene fluoride (PVDF - piezoelectric plastic).

When monitoring sleep states, sleep propensity, respiratory disorders, vigilance state or fatigue of a subject, one or more physiological variables as listed above may be continuously monitored and/or analysed and/or stored.

The present invention allows one or more channels of patient variables and/or events to be monitored, processed and recorded, while at the same time allowing precise data interconnection with a remote site. This remote site can view, process or record the real-time patient data. The communication link can take the form of a range of transmission media, including but not limited to wireless interconnection such as spread spectrum transmission wireless LAN.

The prior art provides devices for the purpose of regulating a patients breathing but these devices are unable to apply principles of acoustic cancellation as proposed by the present invention. While the applicant appreciates that prior systems can monitor patient breathing sound and in particular snoring, these earlier devices were not developed to modulate gas delivery to a patient in a way which can acoustically cancell vibration in the patient's upper palette.

According to the present invention there is provided apparatus for controlling gas delivery to a patient, said delivery being adapted to maintain effective respiratory function, said apparatus including:

means for monitoring one or more physiological variables associated with said patient;

means for deriving from said one or more variables, data representing a respiratory state associated with said patient; and

means for determining from said data, a gas pressure value which substantially prevents a deterioration in said state.

The monitoring means may include means such as a plurality of sensors and/or transducers for acquiring and monitoring variables representing physiological states associated with the patient. The physiological variables can include respiratory effort, breathing airflow, oximetry and/or sound. To this end the

monitoring means includes an air pressure wave or sound/acoustic vibration transducer to monitor breathing sound and/or air pressure waves associated with the patient's respiratory function. The air or sound pressure wave transducer may include a sound microphone, air pressure sensor, air flow sensor or similar device. The air/sound pressure wave transducer may be located near the patient such as being incorporated in the nasal or nasal and oral mask used to deliver gas to the patient, or at any other location suitable for monitoring patient airflow and/or sound. Alternatively or additionally the apparatus may include other respiratory parameters input for the purpose of monitoring and detection of respiratory effort and/or respiratory disorders.

The or each sensor and/or transducer may generate an analog signal representative of variables being monitored. The monitoring means may include means for amplifying and/or performing analog processing on the analog signal. The latter may perform filtering and/or other wave shaping functions. The processed signal may be fed to an analog to digital converter to convert the or each analog signal to a corresponding digital signal. The or each digital signal may be fed to a digital processor such a microprocessor or microcomputer. The digital processor may include software for deriving from the or each digital signal data representing the patients respiratory state. The software may include means such as an algorithm for determining from the data a gas pressure value which substantially prevents a deterioration of the respiratory state. The algorithm may be adapted to generate a gas pressure signal which is substantially 180° out of phase relative to the phase of the patient breathing air flow and/or sound together with an option of a further gas pressure signal which changes relatively slowly when compared to the out of phase signal. The latter may be used to control delivery of gas to the patient to cancel out or substantially compensate the effects of a breathing disorder. In the event that the breathing disorder is not substantially corrected the software may be adapted to activate delivery of a drug such as ventilum. This may circumvent what may otherwise be a fatal or severe asthma attack. The software may additionally be adapted to determine quantity

requirements of the drug. The latter may be based on the patients history and the extent to which the disorder fails to respond to gas pressure treatment.

A preferred embodiment of the present invention will now be described with reference to the accompanying drawings wherein:-

Figure 1 shows a block diagram of one form of gas delivery apparatus according to the present invention;

Figs. 1A to 1F show waveforms associated with the apparatus of Fig. 1;

Fig. 2 shows an overview of system software which may be used in conjunction with the apparatus shown in Fig. 1;

Figs. 3, 3A and 3B show a flow diagram of the sound and respiratory event detector /recorder;

Figs. 4 and 4A show a flow diagram of the respiratory acoustic cancellation feedback servo system; and

Fig. 5 shows one form of gas delivery system modified in accordance with the principles of the present invention.

Referring to Fig. 1 of the drawings, microphone 2 picks up sound from patient 1 and converts this to an electrical signal. The electrical signal from microphone 2 is analog in nature and is passed to signal amplifying and processing module 3.

Amplifying and processing module 3 amplifies the analog signal and performs filtering and/or wave shaping as required. The analog signal then passes to module 5. Module 5 also receives data from one or more sensors and/or transducers adapted to monitor a range of physiological variables associated with patient 1 such as respiratory effort, respiratory airflow, patient oxygen saturation,

brain waves (EEG), heart beat (ECG), eye movement (EOG) muscle function (EMG), patient position and the like. The latter are represented by module 4 which provides analog signals representing the monitored physiological variables to module 5.

Module 5 includes one or more analog to digital convertors and a digital central processing unit (CPU) such as a microprocessor or microcontroller. The CPU is loaded with software including one or more processing algorithms for generating, inter alia, a gas control signal. The gas control signal may be adapted to produce a constant or varying gas pressure and/or air flow as required to compensate a prevailing respiratory disorder.

The gas control signal is fed to pressure transducer 6 to produce a gas pressure which is of a similar frequency but is substantially 180° out of phase relative to the phase of the respiratory signal picked up by microphone 2. The antiphase gas pressure produced by pressure transducer 6 is fed to the patient 1 via a conduit such as a plastics tube and may be applied via the nasal or nasal and oral mask to substantially cancell or compensate the effect of the prevailing breathing disorder. Pressure transducer 6 may include a pressure valve for controlling gas pressure or an acoustic transducer such as a loudspeaker driver.

The apparatus optionally includes a drug delivery module 7 for delivering a drug such as ventilum to patient 1 directly or via the gas feed associated with pressure transducer 6. Drug delivery module 7 receives its control signal from the digital processing unit of module 5. The signal to initiate drug delivery may be based on a consideration of a large number of patient variables available to module 5 via module 4.

Referring to Figs. 1A to 1F, Fig. 1A shows typical sound pressure waveforms associated with a snoring patient. The sound pressure waveforms impinge upon microphone 2. Successive bursts of waveforms are shown separated by a time

"t". Where the time "t" is greater than about 10 seconds this may be interpreted by module 5 of the apparatus as an apnea episode.

Fig. 1B shows the analog electrical signal at the output of microphone 2 which is inputted to amplifying and processing module 3 in Fig. 1.

Fig. 1C shows the (analog) gas control signal outputted by module 5 and inputted to module 6 in Fig. 1.

Fig. 1D shows the actual airflow/ pressure associated with the gas (air) delivered via a conduit from module 6 to patient 1.

Fig. 1E shows the sound pressure waveform of Fig. 1A in which the (horizontal) time axis has been expanded by a factor of 10.

Fig. 1F shows the actual airflow/pressure of Fig. 1D in which the (horizontal) time axis has been expanded by a factor of 10.

A comparison of the waveforms Figs. 1E and 1F shows that at time t_1 a peak in the waveform of Fig. 1E is accompanied by a trough in the waveform of Fig. 1F, illustrating the phase reversal which gives rise to acoustical cancellation and compensates the effects of a prevailing breathing disorder.

Referring to Fig. 2 of the drawings, a combination of the following processes can be operated in real-time either individually or concurrently at any time.

(a) Sound and respiratory event detector/recorder.

(b) Sound and respiratory event detector/recorder replay system.

(c) Acoustic feedback servo system.

The following is a description of each mode of operation with reference to a typical application, being snore detection.

BLOCK 1

Block 1 represents the start of the system processes. Start can be initiated by selecting start recording from system control. Alternatively start process can be initiated by configuring the system to start at a predefined time or the device can be started automatically on power up of the apparatus.

BLOCK 2

Sound and respiratory event detector/recorder

Block 2 represents the system's event detection and recording function mode. The apparatus may be used with minimal memory requirements, in which case the processing capabilities of the system to detect and record the occurrence and frequency of events such as snoring, allows a basic detection device.

For example, the apparatus may be used to monitor patient's breathing sounds and record the events for purpose of a snore index which may allow a physician to determine the extent to which a patient is snoring. The apparatus may detect the frequency and severity (by way of amplitude or sound level measurement) of snoring by a patient. This is the simplest operation mode of the apparatus as memory requirements are minimal. The original sound does not need to be recorded and the apparatus is set up to detect snore events only and count them per unit time such as each hour, for example. By providing to a medical practitioner an indication of how many snores per hour are detected, and the sound level of these snores, the patient can be recommended for further more advanced diagnosis and/or treatment if required.

Alternatively the apparatus can be operated in a mode to store raw data from the input microphone and/or other input sensor(s). This mode of operation can be operated in conjunction with the simpler above mentioned detection mode to allow the medical practitioner to detect a patient's breathing disorders such as

snoring, while at the same time, provide a means of allowing the practitioner to review the patient raw data and validate the detection accuracy of the apparatus.

The former method of detection without the raw data recording function has the advantage of providing a lower cost device in that the memory requirements are less where the device only has to record the occurrence of an event and the time of this occurrence, as opposed to the recording of all the original raw data from the input signal(s).

BLOCK 3

Respiratory Acoustic Cancellation Feedback Servo System (RACFSS)

RACFSS represents a mode of operation which allows the monitoring of a patients breathing sounds such as snoring, while at the same time generating a control signal to provide a modulated gas delivery to a subject. The phase and airflow of the modulated gas delivery to the patient is related to the monitored sound signal from the patient. This is because snoring, due to vibration of the patient's upper palette, can be cancelled out or nulled out by way of an acoustic or pressure waveform of opposite polarity to the original sound source. In the example of snoring, vibration of the upper palette is counteracted by a pressure modulating the patient's palette in opposite polarity to the sound pressure waveforms originating the patient's snoring. This "opposite polarity" pressure or acoustic cancellation can be applied to the patient by way of a nasal mask or full nasal and oral mask. The delivery of the modulated gas to the patient is preferably such that the patient's breathing is stablilised with a minimum amount of gas.

The signal monitored from the patient can be sound, airflow, respiratory effort or other means of detecting the patient breathing.

This control of gas delivery is able to "track" the sound monitored from a patient in such a manner that sound pressure waves produced from the physiological

effects of snoring (for example) can be cancelled out by applying a base pressure with a modulated pressure signal of opposite acoustic phase to the originating patient's snore sound.

While the prior art includes Continuous Positive Air Pressure (CPAP) devices (Sullivan), Variable Positive Air Pressure devices (VPAP), Demand Positive Pressure devices, Autoset (designed by ResMed to automatically adjust CPAP pressure), the apparatus of the present invention is able to apply a modulated pressure waveform with a fast dynamic range and frequency together with a base line pressure, in order to provide acoustic cancellation of patient physiological sounds such as snoring. This type of gas delivery device requires application of unique pressure drivers such as a diaphragm in order to apply the modulation at a frequency high enough to acoustically cancel out a patients snoring with minimal modulated air pressure/flow and minimal base level pressure.

The process of Block 3 can operate individually or in combination with the processes of block 2 or block 4. When Block 3 is operated as an individual process the system is used in a mode of therapeutic control whereupon a subject can be treated for disorders such as apnea, snoring, hypopnea, amongst others.

BLOCK 4

Sound and respiratory event detector/recorder replay system

Block 4 represents the systems capability to provide a means to review:

a) ***monitored raw data*** input from the microphone;

b) review ***events detected by the apparatus*** in order to validate the precision and accuracy of event detection capabilities of the apparatus. This function is helpful to provide to a user of the apparatus a level of validation supporting any diagnostic decision that evolves from the use of the apparatus;

c) ***Selective or random sample event storage.*** This mode of operation allows the apparatus to store one or more selective or random samples of detected events. While only a limited set of raw data samples are stored, all events

may be detected, counted and summarised in terms of events per unit time eg. per hour. This technique may reduce storage requirements significantly while still providing a means for validating a recorded event by recording one or more typical detected events. An example where this function would be useful is where a patient is monitored for snoring but where false detections through excessive background noise could be indicated by allowing the user to review some sample recorded events, which may include excessive background noise, and indicate that the system results should be observed with caution.

* * *

A flow diagram associated with operation of Block 2 (sound and respiratory event detector/recorder) in Fig. 2 is shown in Figs. 3, 3A and 3B. With reference to Figs. 3, 3A and 3B the following is a description of the steps associated with Block 2.

STEP 1

Step 1 represents the system start which could be operated by selecting power on, the pre-programming of a particular start-time, by applying power to the apparatus or alternatively by remote start command.

STEP 2

Step 2 represents converting of data from the input source to a digital format so that this can be further processed in digital mode by the central processing unit of the apparatus. This input data can be, but is not limited to the input from a microphone. Alternatively or additionally the input data can be from other means of detecting patient breathing which could be for example from; an airflow sensor such as a thermistor breathing sensor, thermo-coupler breathing sensor, respiratory effort sensors, sounds recorded from a patient breathing mask (nasal or nasal and oral), a vibration sensor device attached to the patient or other means of monitoring the patient's breathing sounds or physiology.

STEP 3

Step 3 represents primary processing capabilities of the apparatus including the following:

Breathe by Breathe detection

Breathe by breathe analysis allows the "zero crossing" of each breathing cycle to be detected in order to separately classify each patient's breathing cycle. Classifying each breathing cycle allows secondary and tertiary analysis to compare a current patient breathing cycle with a previous breathing cycles in order to determine any change in characteristics of the patient breathing. This is a necessary function when determining whether the application of RACFSS is having the desired affect in relation to stabilising the patient's breathing, ie. is the application of increased and/or modulated air pressure or airflow by way of nasal breathing mask removing the symptoms of snoring, or is the application of ventilum by way of face mask removing the symptoms of asthma (ie is wheezing subsiding). Both these examples are direct applications of RACFSS.

Spectral Analysis (SA)

SA provides a breakdown of the frequency spectrum in terms of amplitude and frequency bands. This type of analysis can also incorporate amplitude or half-period-amplitude analysis. The sample period for spectral analysis can be varied within the processing stages to determine both recognition of instantaneous breathing sound changes and longer term breathing sound changes. The parameters by which the SA processing variables are configured are determined by the user of the apparatus or preset from clinical studies.

Fast Fourier transform (FFT)

FFT is a conventional form of analysis and is provided for the purpose of determining the power monitored at various frequencies. The sample period for the FFT can be varied within the processing stages to determine both recognition

of instantaneous breathing sound changes and longer term breathing sound changes. The parameters by which the FFT processing variables are configured are determined by the user or the apparatus or preset from clinical studies.

Amplitude Determination Analysis

Amplitude of the input microphone signal can be determined for the following conditions;

each period amplitude

each ½ period amplitude

average amplitude over various time intervals (ie . ½ second, 1 second, 5 seconds, 10 seconds, 20 seconds, 30 seconds, 1 minute, 5 minutes).

running average amplitude- ie average level recalculated after each new ½ period or period of monitored signal where the interval for average amplitude can be ½ second, 1 second, 5 seconds, 10 seconds, 20 seconds, 30 seconds, 1 minute, 5 minutes or other durations.

The period over which the signal average is determined can be configured by the user of the apparatus or preset from clinical studies.

Signal to Noise Analysis

Signal to noise analysis can determine normal system noise by shorting out input stage electronics and removing external sound, in order to calibrate the system for external noise against system electronic noise. Advanced signal to noise analysis can also distinguish, in part, patient breathing sounds against unwanted room noise. The determination of background noise can allow accurate threshold calculation in order to precisely set a point at which microphone signal should be ignored.

STEP 4

Step 4 represents an optional capability of the apparatus to store monitored patient data together with primary analysis data onto permanent or semi-permanent devices such as hard disk or removable flash disk devices. This

function is indicated as optional because the apparatus can be configured with no or minimal permanent or semi-permanent storage capabilities in order to reduce the manufacturing cost of the apparatus.

This type of storage is necessary to ensure that raw data from the monitored patient input can be reviewed either remotely or locally during the systems operation or at a later time. The reviewing of the data can be required by the physician or user of the apparatus. A review of this raw data allows a validation of the type of information monitored by the apparatus and also allows the apparatus to indicate to the user where and what events were detected. Thus the user of the apparatus can validate the detection algorithms and processing capability of the apparatus, which is an important factor in the use of the apparatus for providing reliable patient diagnosis.

If, for example, the apparatus is used in noisy environments the number of false event detections may increase and render operation of the apparatus unacceptable. This may be determined by viewing the recorded data and noting whether any events were undetected or falsely detected by utilising an experienced person's capability in scrutinising system performance.

STEP 5

Step 5 represents the system's RAM which can be used to store various processing requirements of the apparatus, together with minimal data storage requirements such as the detection of events, the frequency of detection of events (ie events per hour), random or selective storage of events, patient identification, amongst other storage requirements.

STEP 6

Step 6 represents secondary processing capabilities of the apparatus. This includes an ability to review the output of the primary analysis determined in step

3 above and stored in step 4 and/or 5. The various primary output data needs to be correlated with each type of secondary analysis in order to provide a more accurate means of identifying valid secondary physiological events. For example the recognition of longer term physiological breathing patterns as distinct from shorter term and irregular environmental noise provides a basis of more accurate detection than detections involving less processing and having less discriminatory detection capabilities.

Valid Physiological Breathing Sounds

Valid "physiological breathing sounds" refers to sound recorded from the patient as opposed to back ground electronic system noise and background room noise. Signal to Noise analysis (step 3) deals with calibration of system noise while the calibration of room noise against physiological noise is more complex due to the cast variety of possible room noise. "Physiological breathing sounds" refers to normal breathing sounds and various disordered breathing sounds such as snoring, wheezing, caughing, amongst others. Physiological breathing sounds may be, determined by comparing actual data (refer outputs marked A, B, C, D, F in Fig. 3) to prestored data that characterise various breathing and sleep disorders. The prestored data can be determined by comprehensive clinical trials.

Real-Time Breathe by breathe analysis (frequency and amplitude)

Breathe by breathe frequency analysis can be analysis classification of each breathing cycle in terms of amplitude, spectral and/or fast fourier transform data. These frequency and amplitude characteristics as determined for each breathing cycle (where each breathing cycle is detected in step 6 above) are then collated in terms of frequency and amplitude characterisation for each and every breathing cycle. By characterising each breathing cycle in this manner it is possible to provide a level of background noise discrimination (environmental and electronic system noise). This noise discrimination is possible as breathing noises can be related to the peak and trough points of the breathing cycle, for example. Background noise will not be associated with the breathing cycle as will

physiological breathing noises. This is an example of how noise discrimination can be implemented within step 6.

Environmental sound

Environmental noise is the total sound recorded minus the electronic signal noise and the physiological breathing sounds.

A "patient's sleep state" can be determined by the apparatus by simple means such as arousal detection. These arousal detections can be by way of monitoring additional channels such as movements from a special sensitive mattress. The mattress may be a piezo ceramic or capacitive discharge type. In both these aforementioned mattress types the apparatus is able to monitor the frequency, amplitude and regularity of patient body movements as an indicator as to whether or not the patient is likely to be asleep.

STEP 7

Step 7 represents tertiary processing capabilities of the apparatus. This includes a final analysis by referencing the information from step 6 (which determines valid physiological events as opposed to background and system noise- secondary analysis) and categorises the physiological event data into categories as recognised by medical physicians in the determination of a patients respiratory disorder or sleep disorder diagnosis.

This categorisation can include recognition of an apnea event. The latter is typically recognised by a lapse in breathing during a "patient's sleep state" for a period greater than 10 seconds. In the context of the present invention this could be recognised by detection of snoring sounds punctuated by relative breathing silence for 10 seconds or greater. This type of analysis and categorisation can provide a means of presenting a snoring index or number of snores per hour. The number of snores per hour is recognised by the medical user of the

apparatus as an indicator that the patient is suffering from Obstructive Sleep Apnea for example.

By comparing the patient's current and context (ie the context of the current sound amplitude and frequency with respect to previous sound characteristics) sound amplitude and frequency characteristics with the reference data base characterising various breathing disorders, accurate classification of patient's respiratory disorder is possible. Common, but often under-diagnosed disorders such as asthma can be detected effectively with a simple representation of the present invention by allowing the sound analysis to detect wheezing as could be characteristic of asthma or asthma onset. Wheezing, for example, can be characterised by a pre-stored set of parameters which represent typical characteristics expected when a wheezing signal is detected. These typical wheezing parameters are determined by clinical studies. This technique of comparing a currently monitored patient signal characteristics with the signal characteristics from a range of typical parameters from a sample of respiratory disorders, assists the apparatus of the present invention to provide quick and accurate detection of a number of respiratory disorders with minimal channels required for monitoring (ie in the most common implementation of RACFSS, a simple microphone channel).

Step 7 also has the function of comparing each patient's breathing cycle with a data base of patient breathing characteristics. This data-base of breathing characteristics which may be derived from prior clinical studies, allows matching of frequency and amplitude characteristics of various breathing disorders. In this way a comparison of the current patient's frequency and amplitude characteristics with a known data base of characteristics and associated disorders may assist in accurate diagnosis of the patient's breathing disorders. For example, if the patient is wheezing, the frequency and amplitude characteristics of this sound analysis is likely to match with the reference data base for a diagnostic classification of wheezing, which together with other patient states may lead to the diagnosis of asthma. This diagnosis may lead to the delivery of ventilum.

The output state or event in this case could be high level wheezing. In this example of wheezing RACFSS could be replaced with a ventilum delivery device as the feedback element. The application of ventilum to the patient as the feedback element to cancel out the acoustic symptom of wheezing manifests itself as a precise and accurate method of delivering the absolute minimum but highly responsive treatment of wheezing-related asthma.

The ventilum track algorithm could, for example (in a therapeutic mode of the apparatus) increase or decrease ventilum delivery to the patient until the wheezing state ceases. The optimum value of ventilum delivery could then be stored into a diagnostic ventilum set look-up-table (for later diagnostic reference by the supervising medical practitioner). Various values for ventilum delivery could therefore be determined in this way having regard to each patient state or breathing event.

STEP 8

Step 8 represents a capability of apparatus to store the monitored event type (ie snoring, wheezing, apnea), event time, event duration into hard disk, flash disk or other permanent or semi-permanent storage type.

This function may be optional because as noted above the apparatus can be configured with no or minimal permanent or semi-permanent storage capabilities in order to reduce the manufacturing cost of the apparatus. A review of this raw data allows a validation of the type of information monitored by the apparatus and also allows the apparatus to indicate to the user where and what events were detected. Thus the user of the system can validate the detection algorithms and processing capability of the apparatus, which is an important factor in the use of the apparatus for providing reliable patient diagnosis.

STEP 9

Step 9 represents the system's RAM or other permanent storage facility which can be used to store various processing requirements of the apparatus, together with minimal data storage requirements such temporary storage of tertiary analysis results. Temporary storage can be suitable for the purpose of providing to the user of the apparatus, a means of having a summary of the patient diagnosis. This diagnosis in the simplest form could be, for example, a snoring index (eg. snores per hour).

STEP 10

Step 10 provides "Stop Record" mode. This is achieved by detecting whether the system has a valid pre-programmed stop time, whether the system has been selected for off or whether the system power has been switched off.

STEP 11

Step 11 ends the process and follows step 10 system off selection.

* * *

A flow diagram associated with operation of Block 3 (respiratory acoustic cancellation feedback servo system - RACFSS) in Fig. 2 is shown in Figs. 4 and 4A. With reference to Figs. 4 and 4A, the following is a description of the steps associated with Block 3.

STEP 1

Step 1 represents the system start which could be operated by selecting power on, the pre-programming of a particular start-time, by applying power to the apparatus or alternatively by remote start command.

STEP 2

Step 1 represents the function of the device which detects the system user's selection of therapeutic mode. The selection of therapeutic mode is optional and allows the system to provide control for a gas delivery device, while at the same time providing detection and monitoring of respiratory disorders. The therapeutic function may not be required where the apparatus is to be used as an indicator of snoring or apnea but would be required where the apparatus is to be used for the purpose of monitoring sound while at the same time providing gas delivery control utilising the acoustic cancellation capabilities of the apparatus.

STEP 3

Step 3 analyses input data including microphone input data. The input data is analysed by reviewing the primary, secondary and tertiary results as detailed in the flow diagram of figure 3.

It is necessary to determine whether an event such as snoring has commenced in order to prepare the apparatus to operate in RACFSS mode.

STEP 4

Step 4 decides whether a respiratory event or the start of a respiratory event is detected. The apparatus will prepare itself to track the signal amplitude detected from a respiratory event in order to be able to produce a control signal for the purpose of physiological event cancellation by way of gas delivery.

STEP 5

Step 5 produces the control signal for the purpose of providing an appropriate base level pressure and modulated pressure.

This control signal contains both a base level or low frequency pressure or airflow control and a higher frequency modulated pressure or airflow control. The apparatus produces the control signal for controlling an external device. Alternatively the apparatus could be integrated into a gas delivery device which provides the capability to regulate the pressure or airflow to a patients face mask (ie nasal or full mask).

This pressure control can be similar in frequency and opposite in phase to the original acoustic waves as detected by the microphone. The apparatus should have sufficient processing capability to produce this opposite phase air flow modulation together with a base pressure in order to cancel out physiological events such as snoring with a minimum pressure applied to the patient (ie by way of nasal mask). It is desirable to keep the delivery of pressure to the patient at a minimum in order to minimise the discomfort to the patient and also to minimise side effects from therapeutic intervention by way of gas delivery.

The apparatus of the present invention is unique in its ability to produce a servo loop effect in the application of patient gas delivery. By modulating and controlling the base pressure delivery to minimise the sound monitored during snoring episodes (due to the patient's vibrating upper palette), the apparatus may apply a precise amount of opposite phase modulated pressure to stabilise the vibrating upper palette. The apparatus can provide the combination of base pressure and modulated pressure waveforms by utilising conventional technology to produce a continuous or slowly varying (low frequency) gas delivery - such as a range of pressure (say 0 CMH20 to 20 CMH20 range) with variation of rate of pressure or airflow change from say continuous to 10 cycles per second. At the same time the apparatus may provide a higher frequency modulated gas delivery - such as a range of pressure (say 0 CMH20 to 3 CMH20 range) with variation of rate of pressure or airflow change from say .5 cycles per second to say 1000 cycles per second. The apparatus of the present invention may provide these two forms of gas delivery, being continuous and higher frequency gas modulation. In one form the latter may be provided by means of a diaphragm (similar to the

cone of the driver of an audio loudspeaker) to modulate the low frequency or continuous gas delivery obtainable from a conventional respiratory ventilator or air delivery blower device. One example of the manner in which a continuous gas delivery system may be modified in accordance with the principles of the present invention is described below with reference to Fig. 5.

STEP 6

High frequency pressure rate changes and low frequency base pressure changes may be continuously checked by the system control so as not to exceed pre-programmed patient safety limits. These pressure limits may be detected and checked by way of two methods;

1) System control may limit the amount of base pressure and modulation control output from the system in order to not exceed preset patient limits.
2) The apparatus may monitor gas delivery to the patient by way of a pressure or airflow sensor interfaced to the patients breathing. This interface can be by way of a sensor attached to the patient's breathing mask, for example. The monitored airflow or pressure may be limited by the apparatus to fall within safe patient limits as reprogrammed by the system or the system user (supervising medical practitioner).

STEP 7

Step 7 functions to correct any excessive pressure or airflow modulation to remain within safe patient limits.

STEP 8

Step 8 compares microphone signal's current data with the microphone signal's previous data and determines through processes of comparing alignment and subtraction, whether activated pressure changes are having an effect on the amplitude of the respiratory event. That is, is the effect of pressure activation

change causing the current respiratory event (ie snoring sound) to reduce in presence as measured by a decrease in the amplitude of the sound signal. Reference may be had to the example waveforms shown in Figures 1A to 1F.

STEP 9

Step 9 determines whether pressure or airflow change activation reduce the effect of the respiratory event, ie does snoring subside.

The purpose of this step is to determine whether or not the application of a change of pressure and airflow to the patient is directly related to reducing the symptoms of the patient's respiratory disorder.

STEP 10

Has system "Stop Record" mode or has system pre-programmed stop time been selected or has system power been interrupted or switched off ?

STEP 11

Step 11 ends the process and follows step 10 system off selection.

* * *

Fig. 5 shows one example whereby a continuous gas delivery system can be modified in accordance with the principles of the present invention. Modification is by means of a T section element 50 inserted into the supply of base or continuous pressure or airflow 51 associated with the system. The modification comprises an air pressure modulator 52 (refer module 6 in Fig. 1) placed in communication with the leg of T section element 50 such that air pressure changes produced by modulator 52 are impressed upon the base or continuous pressure or airflow 51 to form a composite pressure/air flow 53. Composite flow 53 comprises a combination of base pressure 51 and modulated pressure/airflow produced via modulator 52. The air pressure changes impressed via modulator

52 are generally of a substantially higher frequency than changes that may be produced by the continuous gas delivery system.

Finally, it is to be understood that various alterations, modifications and/or additions may be introduced into the constructions and arrangements of parts previously described without departing from the spirit or ambit of the invention.

CLAIMS

1. Apparatus for controlling gas delivery to a patient, said delivery being adapted to maintain effective respiratory function, said apparatus including:

means for monitoring one or more physiological variables associated with said patient;

means for deriving from said one or more variables, data representing a respiratory state associated with said patient; and

means for determining from said data, a gas pressure value which substantially prevents a deterioration in said state.

2. Apparatus according to claim 1 wherein said physiological variables include breathing airflow and/or sound.

3. Apparatus according to claim 2 wherein said determining means includes an algorithm adapted to generate a gas pressure signal which is substantially 180° out of phase relative to the phase of said patient breathing and/or sound.

4. Apparatus according to claim 2 wherein said gas pressure value includes a modulated component.

5. Apparatus according to claim 4 wherein said modulated component is of opposite acoustic phase to said patient breathing and/or sound.

6. Apparatus according to claim 4 or 5 wherein said modulated component is adapted to acoustically cancell vibration in the patient's upper palette.

7. Apparatus according to any one of claims 4 to 6 wherein said gas pressure value includes a substantially continuous component and/or a component which changes relatively slowly when compared to said modulated component.

8. Apparatus according to any one of the preceding claims wherein said physiological variables include one or more of brainwaves, heart beat, muscle function and/or patient position.

9. Apparatus according to any one of the preceding claims wherein at least one of said means for deriving and said means for determining is provided via digital processing means.

10. Apparatus according to any one of the preceding claims wherein said deriving means includes an algorithm.

11. Apparatus according to any one of the preceeding claims wherein said deriving means includes means for evaluating sleep and/or arousal states.

12. Apparatus according to any one of the preceeding claims wherein said deriving means includes means for detecting micro arousals.

13. Apparatus according to any one of the preceeding claims wherein said deriving means includes means for detecting respiratory events.

14. Apparatus according to any one of the preceeding claims including a gas delivery means for delivering gas to said patient in accordance with said determined gas pressure.

15. Apparatus according to claim 11 wherein said gas delivery means include a gas pressure valve.

16. Apparatus according to claim 11 wherein said gas delivery means includes an acoustic transducer such as a loudspeaker driver.

17. Apparatus according to any one of the preceeding claims including means for delivering a drug such as ventilum to said patient.

18. Apparatus for controlling drug delivery to a patient, said delivery being adapted to maintain effective respiratory function, said apparatus including:

means for monitoring one or more physiological variables associated with said patient;

means for deriving from said one or more variables, data representing a respiratory state associated with said patient; and

means for determining from said data, a drug quantity which substantially prevents a deterioration in said state.

19. Apparatus according to claim 18 wherein said physiological variables include breathing airflow and/or sound.

20. Apparatus according to claim 18 or 19 wherein said drug includes ventilum.

21. A method for controlling gas delivery to a patient, said delivery being adapted to maintain effective respiratory function, said method including the steps of:

monitoring one or more physiological variables associated with said patient;

deriving from said one or more variables, data representing a respiratory state associated with said patient; and

determining from said data, a gas pressure value which substantially prevents a deterioration in said state.

22. A method according to claim 21 wherein said physiological variables include breathing airflow and/or sound.

23. A method according to claim 22 wherein said determining step includes an algorithm adapted to generate a gas pressure signal which is substantially 180° out of phase relative to the phase of said patient breathing and/or sound.

24. A method according to claim 22 wherein said gas pressure value includes a modulated component.

25. A method according to claim 24 wherein said modulated component is of opposite acoustic phase to said patient breathing and/or sound.

26. A method according to claim 24 or 25 wherein said modulated component is adapted to acoustically cancell vibration in the patient's upper palette.

27. A method according to any one of the preceding claims wherein said gas pressure value include a substantially continuous component.

28. A method according to any one of claims 21 to 27 wherein said physiological variables include one or more of brainwaves, heart beat, muscle function and/or patient position.

29. Apparatus for controlling gas delivery to a patient substantially as herein described with reference to the accompanying drawings.

30. A method for controlling gas delivery to a patient substantially as herein described with reference to the accompanying drawings.

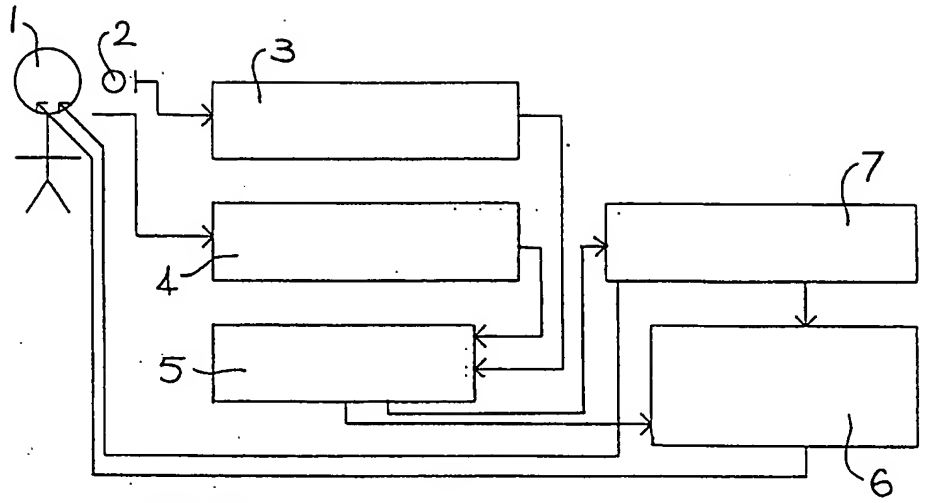
1
2
3
4
5
6
7

FIG 1

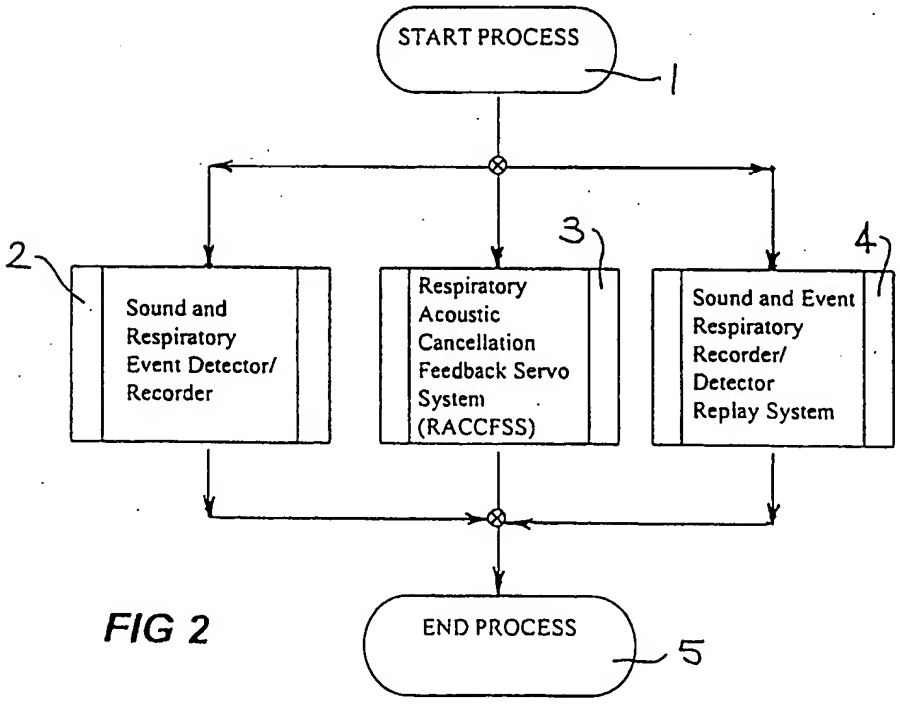
START PROCESS
1
2
Sound and Respiratory Event Detector/ Recorder
3
Respiratory Acoustic Cancellation Feedback Servo System (RACCFSS)
4
Sound and Event Respiratory Recorder/ Detector Replay System
END PROCESS
5

FIG 2

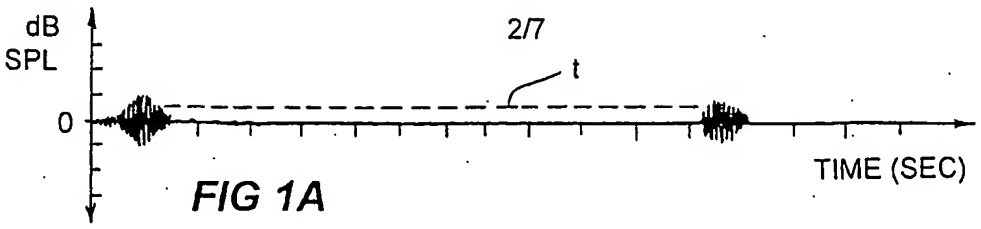

FIG 1A

FIG 1B

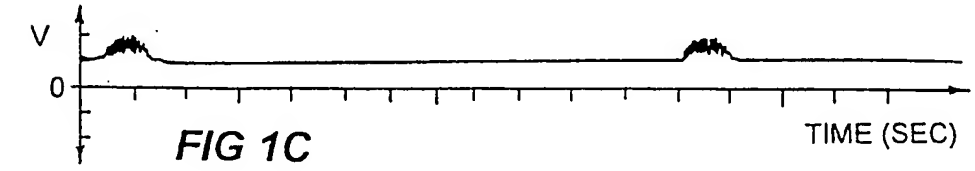

FIG 1C

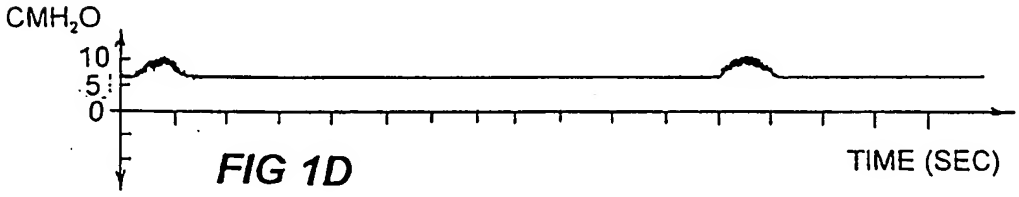

FIG 1D

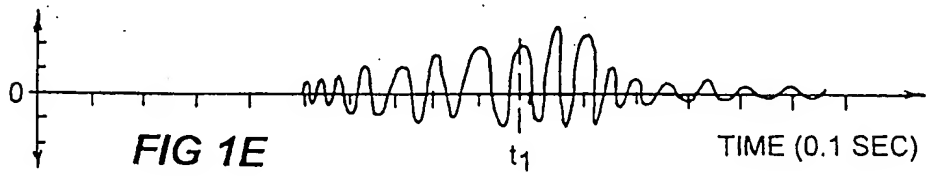

FIG 1E

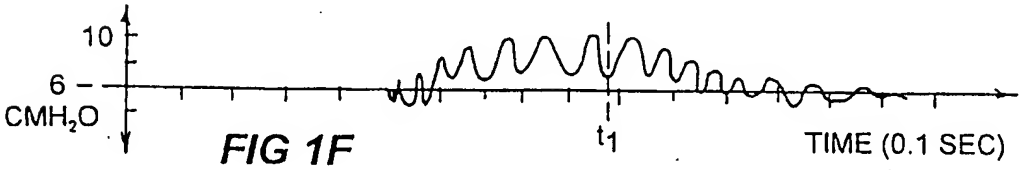

FIG 1F

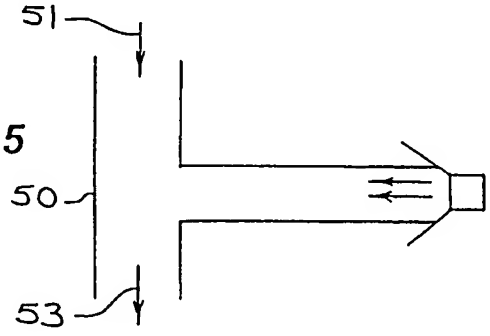

FIG 5

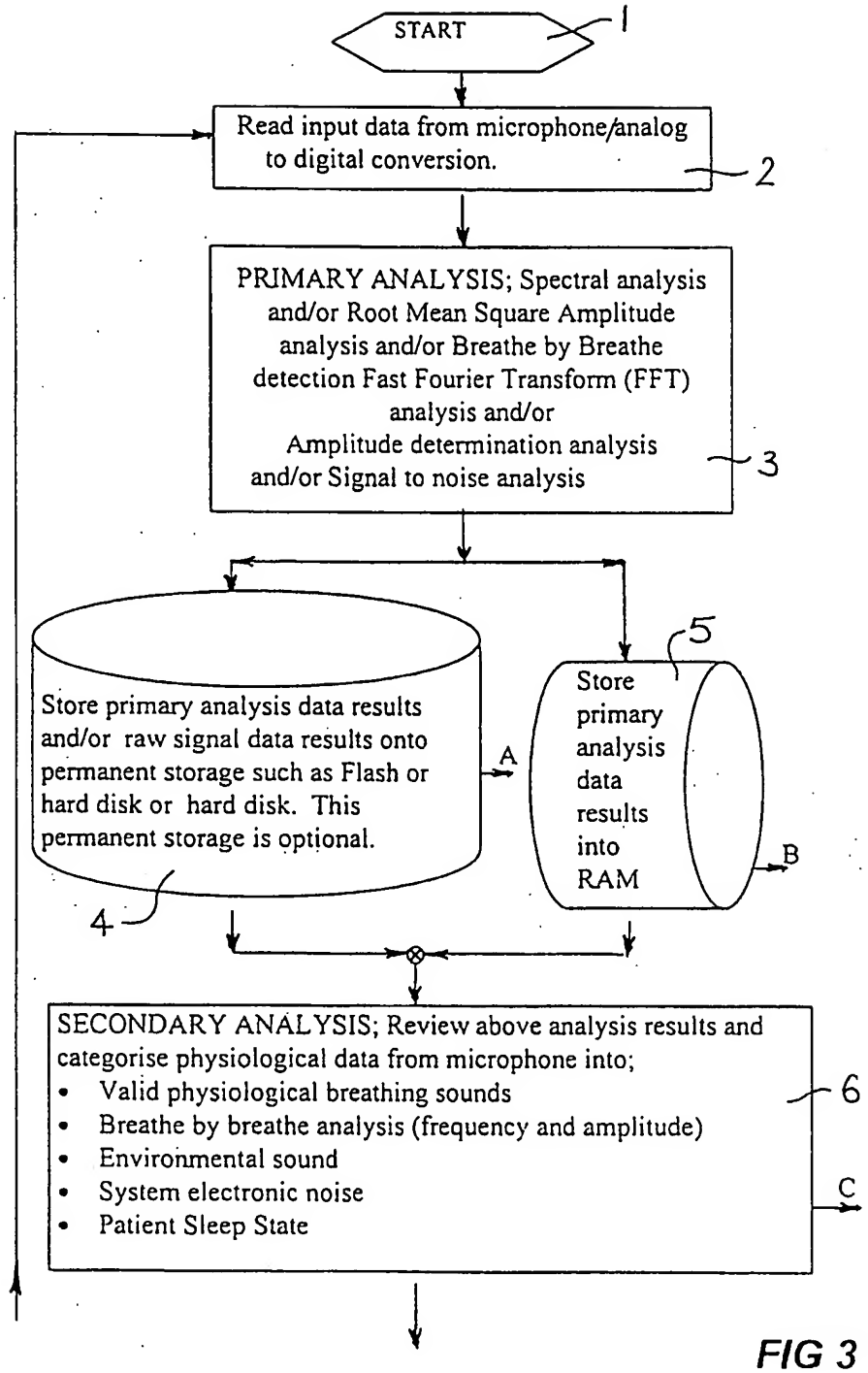
START
1
Read input data from microphone/analog to digital conversion.
2
PRIMARY ANALYSIS; Spectral analysis and/or Root Mean Square Amplitude analysis and/or Breathe by Breathe detection Fast Fourier Transform (FFT) analysis and/or Amplitude determination analysis and/or Signal to noise analysis
3
Store primary analysis data results and/or raw signal data results onto permanent storage such as Flash or hard disk or hard disk. This permanent storage is optional.
4
A
5
Store primary analysis data results into RAM
B
SECONDARY ANALYSIS; Review above analysis results and categorise physiological data from microphone into;
• Valid physiological breathing sounds
• Breathe by breathe analysis (frequency and amplitude)
• Environmental sound
• System electronic noise
• Patient Sleep State
6
C

FIG 3

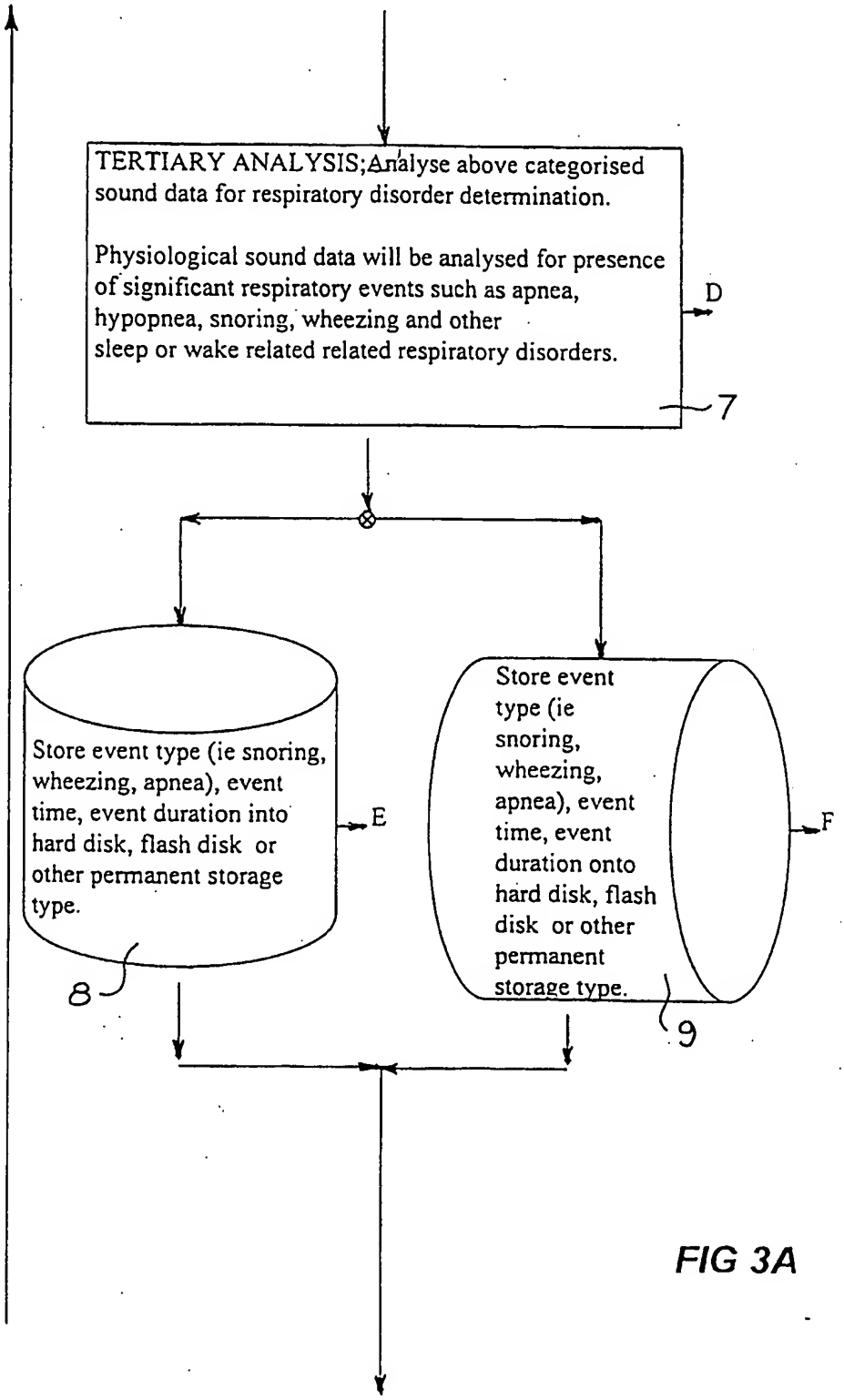
TERTIARY ANALYSIS;Analyse above categorised sound data for respiratory disorder determination.
Physiological sound data will be analysed for presence of significant respiratory events such as apnea, hypopnea, snoring, wheezing and other sleep or wake related related respiratory disorders.
D
7
Store event type (ie snoring, wheezing, apnea), event time, event duration into hard disk, flash disk or other permanent storage type.
E
8
Store event type (ie snoring, wheezing, apnea), event time, event duration onto hard disk, flash disk or other permanent storage type.
F
9

FIG 3A

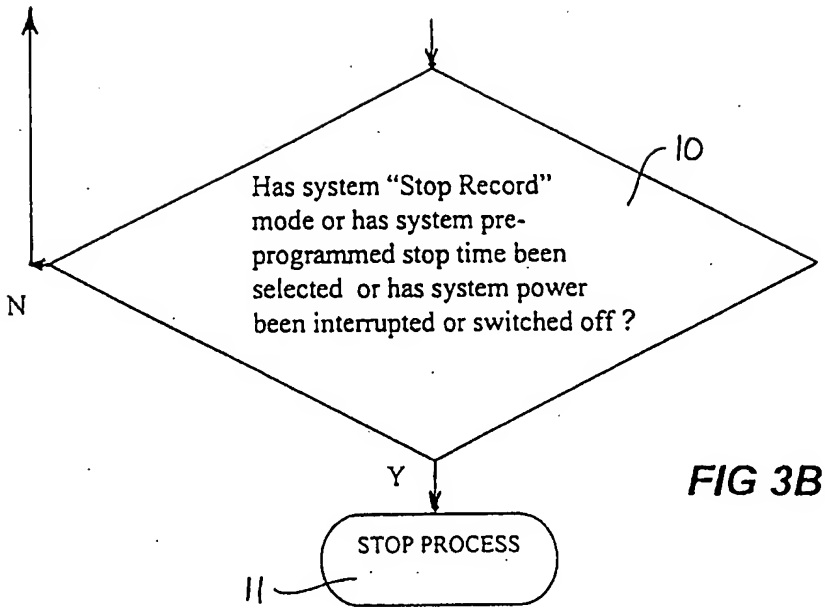
10
Has system "Stop Record" mode or has system pre-programmed stop time been selected or has system power been interrupted or switched off ?
N
Y
STOP PROCESS
11

FIG 3B

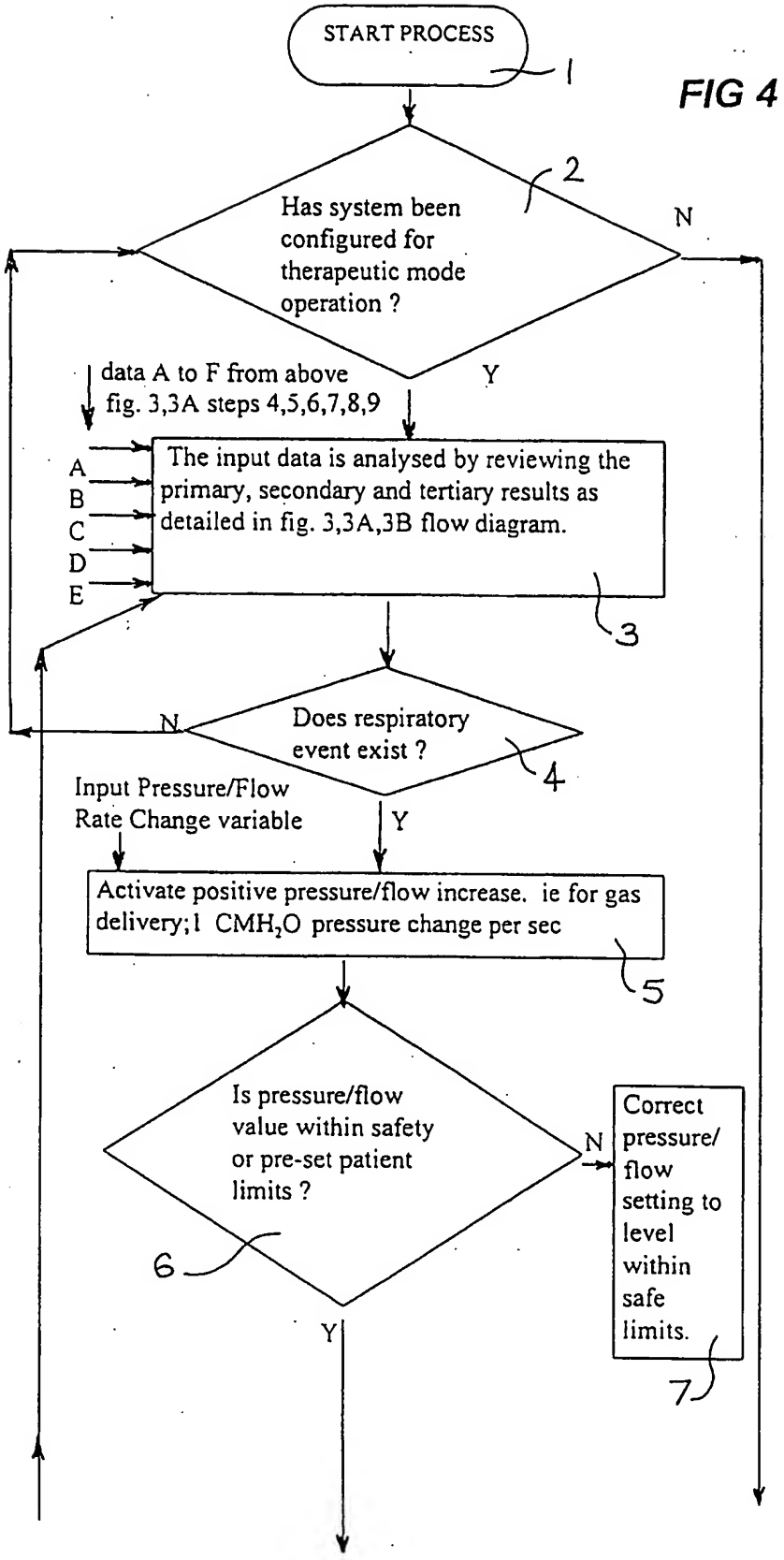
START PROCESS
1
Has system been configured for therapeutic mode operation ?
2
N
Y
data A to F from above fig. 3,3A steps 4,5,6,7,8,9
A
B
C
D
E
The input data is analysed by reviewing the primary, secondary and tertiary results as detailed in fig. 3,3A,3B flow diagram.
3
Does respiratory event exist ?
4
N
Y
Input Pressure/Flow Rate Change variable
Activate positive pressure/flow increase. ie for gas delivery;1 CMH_2O pressure change per sec
5
Is pressure/flow value within safety or pre-set patient limits ?
6
N
Y
Correct pressure/ flow setting to level within safe limits.
7

FIG 4

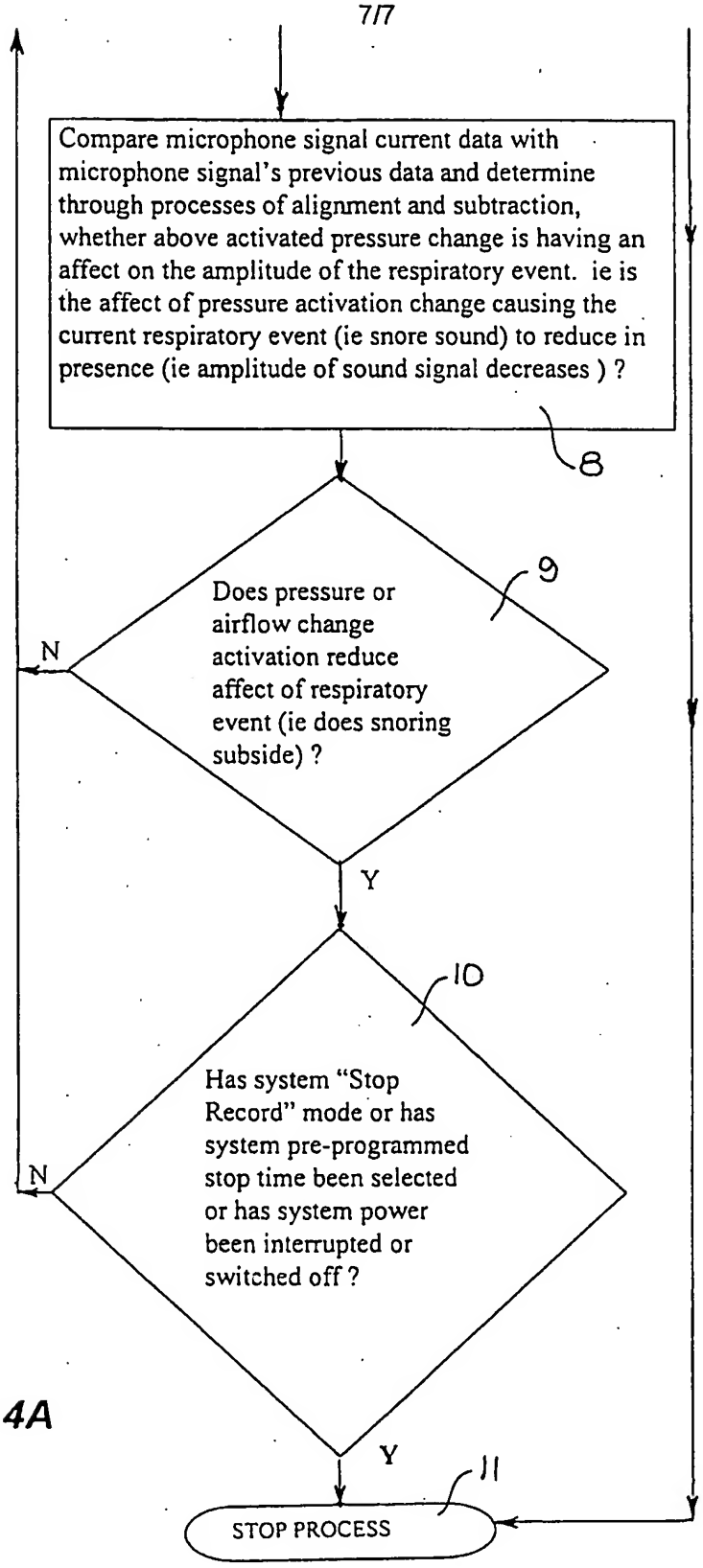
Compare microphone signal current data with microphone signal's previous data and determine through processes of alignment and subtraction, whether above activated pressure change is having an affect on the amplitude of the respiratory event. ie is the affect of pressure activation change causing the current respiratory event (ie snore sound) to reduce in presence (ie amplitude of sound signal decreases) ?
8
Does pressure or airflow change activation reduce affect of respiratory event (ie does snoring subside) ?
9
N
Y
Has system "Stop Record" mode or has system pre-programmed stop time been selected or has system power been interrupted or switched off ?
10
N
Y
STOP PROCESS
11

FIG 4A

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00278

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61M 16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int Cl : A61B 5/-, A61M 16/-, A62B 7/-, 9/-, G10K 11/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU : A61M 16/00

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT : sleep:, monitor:, diagnos:, respir:, breath:, snor:, wheez:, pressur:,
JAPIO : apn:, hypopn:, sound:, acoustic:, etc

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A, 5199424 (SULLIVAN & LYNCH) 6 April 1993 see abstract, fig 5 see column 6 line 29 - column 7 line 57	1, 2, 8-15, 22, 23, 27-28
X	WO,A, 96/40335 (RESPIRONICS INC) 19 December 1996 see page 11 line 19 - page 12 line 21	1, 2, 8-15, 21, 22, 27-28

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 July 1997	16 JUL 1997

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00278

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO, A, 94/23780 (RESPIRONICS INC) 27 October 1994 see abstract, fig 1 see page 8 lines 6-25 see page 12 lines 16-34	1, 2, 8-15, 21, 22, 27-28
X	WO,A, 92/22244 (AXE et al) 23 December 1992 see abstract, fig 1 see page 9 line 20 - page 10 line 19	1, 2, 8-15, 21, 22, 27-28
X	US,A, 5551419 (FROEHLICH et al) 3 September 1996 see abstract, fig 1	1, 2, 8-15, 21, 22, 27-28
X	US,A, 5617846 (GRAETZ) 8 April 1997 see abstract, fig 1 see column 1 line 54 - column 2 line 12	1, 2, 8-15, 21, 22, 27-28
X	US,A, 5353788 (MILES) 11 October 1994 see abstract, fig 4 see column 4 lines 55-66	1, 2, 8-15, 21, 22, 27-28
X	WO, A, 93/09834 (UNIVERSITY TECHNOLOGIES INTERNATIONAL INC) 27 May 1993 see abstract, fig 1A see page 5 lines 7-18 see page 10 lines 7-31 see page 15 line 8 - page 16 line 32	1, 2, 8-15, 21, 22, 27-28
X	WO,A, 93/21982 (NEW YORK UNIVERSITY) 11 November 1993 see whole document	1, 2, 8-15, 21, 22, 27-28
X	WO,A, 92/11054 (PURITAN-BENNETT CORP) 9 July 1992 see whole document	1, 2, 8-15, 21, 22, 27-28
X	US,A, 5490502 (RAPOPORT) 13 February 1996 see abstract, column 2 line 38 - column 3 line 50	1, 2, 8-15, 21, 22, 27-28
A	US,A, 5444786 (RAVIV) 22 August 1995	3-7, 23-26

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00278

Box I **Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1-17, 21-30 are directed to an apparatus and method for controlling the pressure of gas delivered to a patient to prevent deterioration of a monitored respiratory state.

Claims 18-20 are directed to an apparatus for controlling the quantity of a drug to be administered to a patient to prevent deterioration of a monitored respiratory state.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-17, 21-30

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.
PCT/AU 97/00278

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5199424	US WO	5245995 8810108	US	5522382	AU	19894/88
WO	9640335	AU US	60474/96 5537997	CA	2196918	EP	777507
WO	9423780	AU US	66296/94 5458137	CA	2159336	EP	699085
WO	9222244	AU US	21892/92 5203343	CA US	2111324 5458137	EP	592492
US	5551419	AU	40463/95	CA	2163855	EP	722747
US	5617846	CA NO	2157815 953455	EP	705615	FI	954092
US	5353788						
WO	9309834	AU	31270/93	EP	612257		
WO	9321982	AU	42405/93	EP	639088	US	5335654
WO	9211054	US EP	5134995 563044	AU US	82154/91 5259373	AU US	40711/95 5549106
US	5490502	AU WO	42405/93 9321982	EP US	639088 5535739	US US	5335654 5546933
US	5444786						

END OF ANNEX